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Prevalence and risk markers of early psychological distress after ICD implantation in the European REMOTE-CIED study cohort

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ABSTRACT

Background: Evidence on psychological distress in patients living with an implantable cardioverter defibrillator (ICD) is inconclusive. The current study is the first to examine the prevalence and risk markers of anxiety and/or depression in a large international cohort of European ICD patients with or without cardiac resynchronization therapy (CRT).
Method: Heart failure patients (N = 569) from France, Germany, Spain, Switzerland and the Netherlands participating in the REMOTE-CIED study completed a set of questionnaires 1–2 weeks post ICD-implantation, including the 7-item Generalized Anxiety Disorder scale and the 9-item Patient Health Questionnaire to assess anxiety and depressive symptoms, respectively. Patients' clinical data were obtained from their medical records.
Results: The prevalence of anxiety was 16% and that of depression 19%, with 25% of patients reporting one or both types of distress. Multivariable logistic regression analysis showed that age <60 years (odds ratio (OR) = 2.5[95% confidence interval = 1.2–5.0]), having a threatening view of heart failure (OR = 4.7[2.7–8.2]), a high level of ICD-related concerns (OR = 2.9[1.7–5.1]), Type D personality (OR = 2.4[1.3–4.4]), poor patient-reported health status (OR = 2.2[1.3–3.9]) and receiving psychotropic medication (OR = 3.0[1.5–5.9]) were positively associated with distress, while attending cardiac rehabilitation (OR = 0.3[0.2–0.7]) was negatively associated with distress.
Conclusions: A significant subset of European ICD and CRT-defibrillator patients reports anxiety and/or depression in the first weeks post implantation. Patients' psychological characteristics, especially negative perceptions about their illness and treatment, were the strongest associates of distress. Timely identification of these patients is essential as they may benefit from psychological interventions and cardiac rehabilitation in terms of improved quality of life and prognosis.

1. Introduction

Studies have shown that living with an implantable cardioverter defibrillator (ICD) is associated with elevated symptoms of anxiety and/or depression in a subset of patients [1]. However, the prevalence rates of psychological distress based on self-report questionnaires differ greatly across studies, with the prevalence of anxiety ranging from 13 to 63% and that of depression from 5 to 41% [1]. Evidence is inconclusive due to small patient samples with specific selection criteria, varying assessment instruments, timing, and interpretations of 'clinical threshold criteria' for psychopathology, and most studies being conducted in the United States of America (USA) or The Netherlands [1]. Also, the factors associated with distress after ICD implantation are not well understood, yet it seems that sociodemographic and psychological factors have more impact than clinical disease- or ICD-related factors [2–4]. It is unknown whether these relationships differ for ICD patients who do or do not receive cardiac resynchronization therapy (CRT).

It is essential to gain a better understanding of the prevalence and risk markers of psychological distress in ICD and CRT-defibrillator (CRT-D) patients, as it is still unrecognized in cardiac practice and has a negative influence on patients' quality of life and prognosis [5–8]. In addition, research using latent class analyses has shown that distress levels in ICD-patients are relatively stable over time, emphasizing the need for early detection of patients at risk [9,10].

Hence, the current study examines the prevalence and associated factors of early anxiety and/or depression in a large European cohort of 569 ICD and CRT-D patients from France, Germany, Spain, Switzerland and The Netherlands.

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2. Methods

2.1. Study design and participants

Consecutive patients receiving a first-time ICD (single or dual chamber) or CRT-D between April 2013 and January 2016 with symptomatic heart failure (i.e., left ventricular ejection fraction (LVEF) ≤35% and New York Heart Association (NYHA) functional class II or III at time of implantation) comprised the patient sample for the current study. Patients were recruited from five European countries (i.e. France, Germany, Spain, Switzerland and The Netherlands) and participated in the REMOTE-CIED study [11], a randomized controlled trial primarily designed to examine the patient perspective on remote patient monitoring in ICD patients. Patients were excluded if they were younger than 18 or older than 85 years of age, on the waiting list for heart transplantation, had a history of psychiatric illness other than affective/anxiety disorders, or were unable to complete the questionnaires due to cognitive impairments or insufficient knowledge of the language. The study was conducted in accordance with the Declaration of Helsinki and the medical ethics committees of the participating centers approved the study protocol. All patients provided written informed consent. At discharge from hospital after ICD-implantation, participants received a set of questionnaires and were asked to complete this 1 to 2 weeks after implantation to avoid measuring pre-operative distress.

2.2. Materials

2.2.1. Psychological distress

Anxiety and depressive symptoms were assessed using the 7-item Generalized Anxiety Disorder scale (GAD-7) and the 9-item Patient Health Questionnaire (PHQ-9), respectively [12,13]. The items in the GAD-7 and the PHQ-9 reflect the symptom criteria for general anxiety disorder and major depressive disorder, respectively, as outlined in the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) [12,13]. For both scales, items are rated on a 4-point Likert scale from 0 'not at all' to 3 'almost daily' and a cut-off of ≥10 points was used to classify patients with moderate to severe anxiety or depressive symptoms. Using structured psychiatric interviews by mental health professionals as criterion standard, a score of ≥10 has proven to have a sensitivity of 89/88% and a specificity of 82/88% for general anxiety/major depression disorder, respectively [12,13]. In this study, patients are classified as being 'distressed' as they reported clinically relevant anxiety (GAD-7 ≥ 10) and/or depressive (PHQ-9 ≥ 10) symptoms.

2.2.2. Sociodemographic and clinical characteristics

Information on sociodemographic characteristics including age, sex, marital status (single versus having a partner), educational level (secondary school or lower versus tertiary school or higher), and employment status (currently employed versus unemployed) was obtained via purpose-designed questions in the questionnaire. Clinical characteristics were extracted from patients' medical records and entered into an electronic case report form by the local investigators at the participating centers. These characteristics included type of device (ICD versus CRT-D), ICD indication (primary versus secondary prophylactic), NYHA class, heart failure etiology (ischemic versus non-ischemic), QRS duration, LVEF assessed within three months prior to implantation, atrial fibrillation, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, renal disease (glomerular filtration rate <60 mL/min/1.73 m^2), and anemia (hemoglobin value <8.6 mmol/L for males or <7.4 mmol/L for females). Finally, patients were asked in the questionnaire if they are or have been attending a cardiac rehabilitation program.

2.2.3. Patient-reported health status

The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to assess heart failure-specific health status. The KCCQ is a 23-item, self-report questionnaire that quantifies physical limitation, symptoms, social function, and quality of life of patients with heart failure [14]. These four health status subscales can be combined into a single overall summary score ranging from 0 to 100, with higher scores representing better health status. Poor health status was defined as a KCCQ score <50 points [15].

2.2.4. Lifestyle factors

Information on patients' lifestyle, including their body mass index, smoking status and use of alcoholic beverages was obtained from purpose-designed questions in the questionnaire. In addition, patients completed the 12-item European Heart failure Self-care Behavior Scale (EHFScBS-12) [16]. The items on this scale (e.g. "I weigh myself every day.") are rated on a 5-point Likert scale, with the total score ranging from 12 to 60 and a higher score indicating worse self-care behavior.

2.2.5. Psychological characteristics

In the questionnaire, patients were asked if they currently use psychotropic medication (i.e., antidepressants, anxiolytics and/or hypnotics) or are treated for psychological problems by a social worker, psychologist or psychiatrist. This information may be interpreted as a proxy measure for prior or existing affective/anxiety problems.

In addition, patients completed a set of validated and standardized questionnaires to assess the distressed (Type D) personality characteristics and patients' perceptions of their heart failure and ICD. *Type D personality* was measured using the 14-item Type D Scale (DS14) [17]. The items on this scale are rated on a 5-point Likert scale ranging from 0 'false' to 4 'true' and can be divided into two 7-item subscales: negative affectivity (e.g., "I am often irritated") and social inhibition (e.g., "I find it hard to start a conversation"). Type D personality is defined with a score of ≥10 on both subscales.

The brief Illness Perception Questionnaire (B-IPQ) was used to assess *patients' beliefs about their heart failure*. It consists of eight items rated on a 0–10 response scale, assessing cognitive (e.g., "How long do you think your illness will continue" and "How much control do you feel you have over your illness?") and emotional (e.g., How concerned are you about your illness?") illness representations and illness comprehensibility (i.e., "How well do you think you understand your illness?") [18]. An overall score ranging from 0 to 80 was computed with a higher score reflecting a more threatening view of heart failure.

Patient acceptance of their ICD was assessed with the 12-item Florida Patient Acceptance Survey (FPAS) [19]. Items (e.g., "My device was my best treatment option.") are rated on a 5-point Likert scale from 1 'strongly disagree' to 5 'strongly agree' with higher total scores indicating better device acceptance. *Patients' concerns regarding their ICD giving a shock* was measured using the 8-item ICD concerns questionnaire (ICDC), which is a brief version of the 20-item original questionnaire [20]. Items (e.g. "I am worried about my ICD firing.") are scored on a 5-point Likert scale from 0 'not at all' to 4 'very much so'. The total score ranges from 0 to 32, with a higher score indicating a higher level of concerns.

2.3. Statistical analyses

Characteristics of the study sample are summarized as frequencies with percentages for categorical variables and medians with interquartile ranges (IQR) for continuous variables. Pearson's Chi-square tests (or Fisher's exact test if appropriate) for categorical variables and Mann Whitney *U* tests for continuous variables were used to compare the characteristics of distressed and non-distressed patients. Multivariable logistic regression analyses were performed to examine which sociodemograpic, clinical and psychological characteristics were independently associated with early psychological distress after ICD implantation. All baseline characteristics were included as covariates, except for LVEF that had too many missing values (17%). Due to non-normality and in order to enhance the interpretability of the results, we dichotomized all continues variables using pre-specified cut-offs.

Age was dichotomized into <60 years versus ≥60 years, QRS duration into ≤120 ms versus >120 ms, and body mass index into <30 versus ≥30. For questionnaires without a predefined cut-off value, tertiles were used for dichotomization. Patients scoring in the highest tertile of the EHFScBS-12 (>29), the IPQ (>45) and the ICDC (>13) were defined as having poor self-care behavior, a threatening view of their illness, and a high level of ICD-related concerns, respectively. Patients scoring in the lowest tertile of the FPAS (<60) were defined as having poor acceptance of their device. The odds ratios (OR) and their corresponding 95% confidence intervals (CI) are reported. To examine whether results differ for anxiety versus depression, all analyses were repeated for patients reporting anxiety or depression only. In addition, we examined whether the prevalence and risk markers of distress varied for ICD versus CRT-D patients. All tests were two-tailed with $p < 0.05$ indicating statistical significance. Analyses were performed with SPSS 21.0 for Windows (SPPS Inc., Chicago, Illinois).

3. Results

3.1. Patient characteristics and prevalence of psychological distress

In total, 633 patients signed informed consent for the REMOTE-CIED study, of which 599 (95%) returned the completed questionnaire set. Four of these patients (0.7%) had to be excluded as they did not meet essential in- and exclusion criteria. Of the remaining 595 patients, 26 (4%) did not complete the PHQ9 and/or the GAD7 and were excluded from the analyses. Our final sample comprised 569 patients with a median age of 66 (IQR = 59–73) years, 119 (21%) patients were female, 218 (38%) patients received a CRT-D, and in 82 (14%) patients the ICD indication was secondary prophylactic. The median time between implantation and completion of the questionnaires was 11 days (IQR = 5–17 days).

At this time, 142 (25%) of the patients reported psychological distress, of which 35 patients (25%) reported anxiety symptoms only, 51 patients (36%) reported depressive symptoms only and 56 patients (39%) reported both. Hence, the prevalence of depression is 19% ((51 + 56)/569) and that of anxiety is 16% ((35 + 56)/569)) in the current sample. Of note, the prevalence of distress significantly differed between the countries ($p = 0.006$), with the prevalence being 19% in Dutch, 34% in German, 32% in French, 30% in Spanish and 23% in Swiss patients. The prevalence of anxiety was particularly high in French patients (26%), while depression had a high prevalence in German patients (31%).

Sociodemographic, clinical, lifestyle, psychological and treatment characteristics of the total sample, and stratified by psychological distress are shown in Table 1. Distressed patients had a lower median age and were more likely to be female, but less likely to have a high educational level compared with non-distressed patients. The only significant group differences in clinical characteristics were that distressed

Table 1
Clinical and psychosocial characteristics of the total sample, and stratified by distress.

	Total sample $N = 569$	Distressed[a] $N = 142$	Non-distressed $N = 427$	p-value
Sociodemographic characteristics				
Age (years)	66 (59–73)	**64 (54–72)**	**66 (60–73)**	**0.006**
Female	119 (21)	**45 (32)**	**74 (17)**	**<0.001**
Having a partner	420 (74)	97 (68)	323 (76)	0.09
High educational level (tertiary)	348 (61)	**76 (54)**	**272 (64)**	**0.03**
Employed	119 (21)	28 (20)	91 (21)	0.69
Heart disease characteristics				
Cardiac resynchronization therapy	218 (38)	49 (35)	169 40)	0.28
Secondary prophylactic ICD indication	82 (14)	25 (18)	57 (13)	0.21
Ischemic heart failure etiology	319 (56)	77 (54)	242 (57)	0.61
QRS duration (ms)	120 (103–154)	116 (100–144)	121 (104–156)	0.07
Ejection fraction (104 missing)	27 (22 − 31)	29 (24–32)	27 (21 − 30)	0.12
New York Heart Association class III	191 (34)	**59 (42)**	**132 (31)**	**0.02**
Poor health status[b]	201 (35)	**85 (60)**	**116 (27)**	**<0.001**
Comorbidities				
Diabetes mellitus	184 (32)	50 (35)	134 (31)	0.40
Chronic obstructive pulmonary disease	78 (14)	19 (13)	59 (14)	0.90
Renal disease	140 (25)	31 (22)	109 (26)	0.38
Atrial fibrillation	158 (28)	38 (27)	120 (28)	0.76
Hypertension	327 (58)	86 (61)	241 (56)	0.39
Anemia	60 (11)	17 (12)	43 (10)	0.52
Lifestyle				
Body mass index >30	142 (25)	37 (26)	105 (25)	0.73
Smoking	92 (16)	27 (19)	65 (15)	0.29
Use of alcohol	273 (48)	**53 (37)**	**220 (52)**	**0.003**
Self-care behaviour[c]	25 (20 − 32)	26 (19–33)	25 (20–32)	0.58
Psychological status				
Type D personality[d]	116 (20)	**60 (43)**	**56 (13)**	**<0.001**
Ilness perceptions[e]	41 (33–48)	**49 (44–54)**	**38 (29–45)**	**<0.001**
ICD concerns[f]	9 (3–17)	**16 (7–23)**	**7 (2 − 13)**	**<0.001**
Device acceptance[g]	65 (54–73)	**58 (48–65)**	**67 (58–75)**	**<0.001**
Treatment				
Psychotropic medication[h]	87 (15)	**39 (28)**	**48 (11)**	**<0.001**
Psychological treatment	27 (5)	**17 (12)**	**10 (2)**	**<0.001**
Cardiac rehabilitation	117 (21)	24 (17)	93 (22)	0.22

Results presented as n(%) for categorical variables, and as median(interquartile range) for continuous variables. Significant results are presented in bold.
[a] Distressed: anxious (Generalized Anxiety Questionnaire >10) and/or depressed (Patient Health Questionnaire >10).
[b] Poor health status: total score Kansas City Cardiomyopathy Questionnaire <50.
[c] Self-care behavior: total score European Heart Failure Self Care Behavior Scale.
[d] Type D personality: score of >10 on both negative affectivity and social inhibition subscales of Type D scale.
[e] Illness perceptions: total score brief Illness Perceptions Questionnaire.
[f] ICD concerns: total score on ICD concerns scale.
[g] Device acceptance: total score on Florida Patient Acceptance Scale.
[h] Psychotropic medication: antidepressants, anxiolytics and/or hypnotics.

patients were more likely to have NYHA class III heart failure symptoms and to report poor health status. Looking at lifestyle and psychological characteristics, distressed patients were less likely to drink alcohol, yet more likely to receive psychological treatment or medication and to have a Type D personality. Finally, distressed patients had a more threatening and negative view of their heart failure and ICD compared with non-distressed patients, as indicted by higher median scores on the brief IPQ and ICDC scales and a lower FPAS score.

When examining depression and anxiety separately, we found the same group differences, yet depressed patients were less likely to have a partner compared with non-depressed patients, gender and NYHA class were not associated with anxiety, and educational level was not associated with being depressed or anxious.

3.2. Independent risk markers of psychological distress

Multivariable logistic regression analysis (Table 2) indicated that younger age, having poor health status, Type D personality, a threatening view of heart failure, a high level of ICD-related concerns, and receiving psychological medication were independently associated with increased odds of psychological distress. Attending cardiac rehabilitation was associated with decreased odds of psychological distress. Sensitivity analyses including non-dichotomized independent variables did not change our overall conclusion; only age was no longer associated with psychological distress.

When looking separately at anxiety, poor health status (OR = 1.91, 95% CI = 1.02–3.57, $p = 0.04$), a more threatening view of heart failure (OR = 4.30, 95% CI = 2.27–8.15, $p < 0.001$), a high-level of ICD-related concerns (OR = 3.69, 95% CI = 1.99–6.85, $p < 0.001$), and using psychotropic medication (OR = 2.95, 95% CI = 1.45–5.99, $p = 0.003$) were positively associated with anxiety. Attending cardiac rehabilitation (OR = 0.38, 95% CI = 0.18–0.81, $p = 0.01$) was negatively associated with anxiety.

Younger age (OR = 2.95, 95% CI = 1.35–6.43, $p = 0.007$), secondary prophylactic ICD indication (OR = 2.22, 95% CI = 1.02–4.83, $p = 0.04$), Type D personality (OR = 2.56, 95% CI = 1.36–4.81, $p = 0.004$), a more threatening view of heart failure (OR = 4.91, 95% CI = 2.61–9.22, $p < 0.001$), poor ICD acceptance (OR = 2.45, 95% CI = 1.34–4.49, $p = 0.004$), and receiving psychological medication (OR = 2.52, 95% CI = 1.20–5.28, $p = 0.01$) were positively associated with depressive symptoms. Drinking alcohol (OR = 0.43, 95% CI = 0.23–0.80, $p = 0.01$) and attending cardiac rehabilitation (OR = 0.49, 95% CI = 0.24–0.99, $p = 0.05$) were negatively associated with depression.

3.3. ICD versus CRT-D patients

The prevalence of psychological distress did not significantly differ for patients with or without CRT (23% versus 27%, $p = 0.28$). As

Table 2
Risk markers of early psychological distress[a] in the total sample, ICD and CRT-D patients.

	Total sample ($N = 569$)			ICD patients ($N = 351$)			CRT-D patients ($N = 218$)		
	OR	95% CI	*p*-value	OR	95% CI	*p*-value	OR	95% CI	*p*-value
Sociodemographic characteristics									
Age < 60 years	**2.45**	**1.19–5.02**	**0.02**	**3.53**	**1.37–9.10**	**0.009**	1.84	0.43–7.76	0.41
Female	1.69	0.90–3.17	0.10	**3.58**	**1.51–8.45**	**0.004**	0.41	0.12–1.46	0.17
Having a partner	0.93	0.52–1.67	0.80	1.81	0.80–4.09	0.15	**0.31**	**0.10–0.93**	**0.04**
High educational level	0.77	0.44–1.36	0.37	0.60	0.29–1.25	0.17	1.24	0.41–3.75	0.71
Employed	0.60	0.28–1.30	0.20	0.64	0.24–1.74	0.64	0.39	0.07–2.00	0.26
Heart disease characteristics									
Cardiac resynchronization therapy	0.82	0.42–1.59	0.55	–	–	–	–	–	–
Secondary prophylactic ICD indication	1.94	0.95–3.98	0.07	1.74	0.67–4.53	0.26	1.54	0.29–8.09	0.61
Ischemic heart failure etiology	0.96	0.55–1.68	0.88	1.15	0.55–2.40	0.72	0.69	0.21–2.26	0.54
QRS duration >120 ms	0.86	0.46–1.61	0.64	1.55	0.71–3.37	0.27	**0.24**	**0.06–0.92**	**0.04**
New York Heart Association class III	1.02	0.56–1.83	0.95	1.26	0.57–2.81	0.57	1.10	0.36–3.31	0.87
Poor health status[b]	**2.22**	**1.26–3.91**	**0.006**	1.98	0.91–4.31	0.09	**4.03**	**1.41–11.51**	**0.009**
Comorbidities									
Diabetes mellitus	1.23	0.69–2.19	0.48	1.03	0.49–2.18	0.94	1.64	0.50–5.32	0.41
Chronic obstructive pulmonary disease	0.59	0.26–1.35	0.21	0.43	0.14–1.31	0.14	0.57	0.12–2.81	0.49
Renal disease	0.70	0.35–1.38	0.30	0.77	0.31–1.91	0.57	0.53	0.13–2.14	0.37
Atrial fibrillation	1.48	0.81–2.70	0.21	1.56	0.68–3.60	0.30	1.16	0.35–3.82	0.81
Hypertension	1.06	0.61–1.85	0.83	0.72	0.35–1.47	0.37	2.65	0.82–8.54	0.10
Anemia	1.24	0.52–2.94	0.63	2.02	0.61–6.74	0.25	0.93	0.18–4.76	0.93
Lifestyle									
Body mass index >30	0.70	0.38–1.28	0.25	0.92	0.41–2.08	0.84	0.45	0.13–1.58	0.21
Smoking	0.81	0.38–1.71	0.58	0.91	0.37–2.25	0.84	1.02	0.18–5.96	0.98
Use of alcohol	0.74	0.43–1.28	0.27	0.66	0.32–1.35	0.25	0.76	0.23–2.46	0.65
Poor self-care behavior[c]	0.86	0.49–1.51	0.60	1.21	0.59–2.51	0.60	0.27	0.07–1.02	0.05
Psychological status									
Type D personality[d]	**2.43**	**1.34–4.40**	**0.003**	**2.77**	**1.26–6.12**	**0.01**	2.89	0.88–9.48	0.08
Threatening view of heart failure[e]	**4.66**	**2.65–8.20**	**<0.001**	**4.31**	**1.99–9.33**	**<0.001**	**10.74**	**3.21–35.82**	**<0.001**
High level of ICD-related concerns[f]	**2.94**	**1.70–5.09**	**<0.001**	**2.79**	**1.31–5.92**	**0.008**	**5.48**	**1.79–16.76**	**0.003**
Poor device acceptance[g]	1.32	0.76–2.30	0.33	1.96	0.94–4.10	0.07	0.87	0.28–2.70	0.82
Treatment									
Psychotropic medication[h]	**2.95**	**1.49–5.86**	**0.002**	**4.05**	**1.60–10.26**	**0.003**	3.03	0.85–10.77	0.09
Psychological treatment	2.93	0.93–9.22	0.07	12.15	**2.19–67.47**	**0.004**	1.13	0.07–17.50	0.93
Cardiac rehabilitation	**0.32**	**0.16–0.65**	**0.001**	**0.25**	**0.10–0.63**	**0.003**	0.34	0.08–1.44	0.14

Significant results are presented in bold.

[a] Distress: anxiety (Generalized Anxiety Questionnaire >10) and/or depression (Patient Health Questionnaire >10).
[b] Poor health status: total score Kansas City Cardiomyopathy Questionnaire <50.
[c] Poor self-care behavior: total score European Heart Failure Self Care Behavior Scale >29.
[d] Type D personality: score of >10 on both negative affectivity and social inhibition subscales of Type D scale.
[e] Threatening view of heart failure: total score brief Illness Perceptions Questionnaire >45.
[f] High level of ICD-related concerns: total score on ICD concerns scale >13.
[g] Poor device acceptance: total score on Florida Patient Acceptance Scale <60.
[h] Psychotropic medication: antidepressants, anxiolytics and/or hypnotics.

shown in Table 2, having a more threatening view of heart failure and a high level of ICD-related concerns were related to distress in both ICD and CRT-D patients, with higher ORs in CRT-D patients. In ICD patients, younger age, female gender, Type D personality, receiving psychological treatment/medication and not attending cardiac rehabilitation were also significant risk markers of distress. While in CRT-D patients, being single, having a QRS-duration <120 ms, and a poor health status were associated with increased odds of distress.

4. Discussion

In the current study on a large sample of European ICD and CRT-D patients participating in the REMOTE-CIED study, the prevalence of anxiety was 16% and that of depression was 19%, with 25% of patients reporting one or both types of distress in the first month post-implantation. As expected, psychological and patient-reported factors, i.e. illness perceptions, psychotropic medication use, ICD-related concerns, Type D personality and patient-reported health status, were the strongest associates of distress. Importantly, cardiac rehabilitation attendance was associated with decreased odds of distress.

The prevalence rates of anxiety and depression in ICD patients vary widely across studies, also depending on the type, interpretation, and timing of the instrument used to measure psychological distress [1]. The current study is the first study that used the GAD-7 and the PHQ-9 to assess early anxiety and depression in ICD patients. The prevalence rates (16 and 19%, respectively) are in line with the prevalence of ~20% found in the small number of studies that have used structured interviews to diagnose anxiety and depressive disorders in ICD patients [1]. Other studies on early distress in ICD patients found much higher prevalence rates, for example those using the Spielberger State Trait Anxiety Inventory showing elevated anxiety scores in 30–50% of the patients [21–24]. This might be due to the questionnaire scores being confounded by comorbid depression and reduced physical wellbeing [25,26]. Also, the vast majority of studies on distress in ICD patients so far have assessed distress ≥12 months post-implantation [1]. For example, one recent study used the GAD-7 to assess anxiety in 670 US patients at a median time of 3.2 years post ICD-implantation, and showed that only 7–10% of these patients reported moderate to severe anxiety [27]. This suggests that distress levels might decrease after the first year post-implantation, which has been shown in some [28,29], but not all longitudinal studies [30,31]. Recent research using latent class analyses indicates that psychological distress after ICD implantation is relatively stable and that baseline levels of distress give a good indication of how distress levels will generally evolve over time [9,10]. This indicates that screening for distress in the first weeks post-implantation, as was done in the current study, is feasible to identify patients at risk for chronic distress. Results of the screening could then be discussed during patients' first in-clinic ICD check-up and timely adjunctive psychological interventions could be offered.

The prevalence of ~20% for anxiety and depression in ICD and CRT-D patients mirrors the rate found in other cardiac patient groups, including congestive heart failure without ICD and post-myocardial infarction patients [32–34]. This and evidence showing that patients are generally well able to cope with ICD shocks [35] and advisories [36], suggests that the impact of being faced with ICD shocks or living with a technical device should not be overestimated [37]. Shocks were not included in the current analyses due to the short time since implantation, but previous studies including a recent Swedish study with >3000 ICD patients showed that not the occurrence of shocks, but patients' concerns on receiving shocks are most important in explaining their adjustment to the device [38]. In the latter study, ICD-related concerns explained 54–68% of the relationship between shocks and psychological distress [38].

Besides patients' concerns about the ICD, negative illness perceptions (i.e. perceiving heart failure as burdensome, and having a sense of lack of control over it) and Type D personality (i.e. a tendency towards negative affectivity and inhibition of self-expression in social situations) were strongly associated with psychological distress in the current study. This finding underlines previous research showing that illness perceptions and Type D personality are associated with adverse physical and emotional health outcomes in cardiac patients, which may be mediated by inadequate coping and poor self-care behavior [39–43]. Yet, evidence on the relationship between psychological factors and self-care behavior is inconsistent. Although it is generally assumed that psychological distress is related to poor self-care, some studies show opposite results [44]. For example, alcohol consumption was negatively related to depression in the current sample, which confirms a large Italian study in heart failure patients showing that moderate wine consumption is associated with better health and a lower prevalence of depression [45]. Moderate alcohol consumption could indicate a better social life and less concerns about health in non-depressed patients.

The risk markers of distress differed somewhat between ICD and CRT-D patients. The most important difference was that indicators of heart failure severity, i.e., QRS ≤ 120 ms, poor patient-reported health status and having a threatening view of heart failure, were (more strongly) related to distress in CRT-D patients. This suggests that suffering from heart failure plays a more prominent role in the lives of patients receiving CRT. This might be especially true for CRT-patients with narrow QRS complexes (15% of the CRT patients in our sample) as their physicians decided to offer them CRT despite current guidelines restricting this treatment to patients with broad QRS complexes (≥120 ms) [46]. The effects of CRT in patients with narrow QRS complexes on patient-reported outcomes should be investigated in larger studies.

Overall, the current and previous results indicate that especially those patients who are younger, have negative beliefs about their ICD and heart failure, a Type D personality or a history of psychological distress are vulnerable to experience anxiety and/or depression post ICD-implantation. These patients should be identified in clinical practice and offered appropriate and timely interventions, starting with the provision of adequate and specific patient education. Research emphasizes that there is still a lot to win in this area, as the psychosocial consequences of living with an ICD or heart failure are often not discussed with patients, and psychological distress is undertreated in clinical practice [3,5,6,47]. Also, only a minority of ICD patients attends cardiac rehabilitation programs (21% in this study, with even lower rates (10–15%) in countries outside of The Netherlands), while such programs are associated with a lower risk of psychological distress, as was also shown in the current study. Particularly, exercise training combined with a psychological intervention seems to be beneficial for ICD and heart failure patients [48]. These interventions should be targeted to individual patients' needs and preferences and include cognitive restructuring and stress management techniques in order to address their negative illness and treatment beliefs and improve their coping skills [49,50]. (Individualized) cardiac rehabilitation programs as a potential means against psychological distress should be investigated in future prospective trials.

Limitations of the current study include its cross-sectional nature, missing information on ICD-shocks, and the majority of patients (54%) being included in the Netherlands preventing us to do multivariable analyses for the separate countries. Our finding that the prevalence of depression was particularly high in German patients and that anxiety was reported by a relatively high number of French patients emphasizes the need for ICD-studies on psychological distress in European countries outside of the Netherlands. Yet, the current study is the first study to include patients from various European countries and to compare the prevalence and an elaborate set of sociodemographic, clinical and psychological risk markers of distress in ICD versus CRT-D patients.

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Conflicts of interest

The authors report no relationships that could be construed as a conflict of interest.

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